

REMARKS

Applicants have studied the Office Action mailed July 16, 2002. It is respectfully submitted that the application is in condition for allowance. Reconsideration and allowance of the pending claims in view of the above amendments and the following remarks is respectfully requested.

Informalities/Objections:

Drawings:

The Examiner states that the preliminary amendment filed May 22, 2002 to amend the drawings has not been entered, and that new drawings would be required to introduce the proposed amendment.

In response, Applicants intend to submit formal drawings, having Sequence Identifiers (SEQ ID NOS:) inserted where relevant, upon allowance of the presently rejected claims.

Hyperlinks:

The Examiner objected to the disclosure as containing an embedded hyperlink and/or other form of browser-executable code.

Applicants have deleted the hyperlinks from the specification, as indicated above by the replacement paragraphs. The URL's are not needed for enablement of the claimed invention, but merely provided additional background information.

Sequence Rules:

The Examiner objected to the specification as not complying with 1.821(d) of the Sequence Rules and Regulations because pages 3 and 4 contain amino acid sequences without an assigned identifier.

In response, Applicants submit herewith a substitute Sequence Listing having the amino acid Sequences presented on pages 3 and 4 of the specification, as well as the amino acid sequence fragments presented in Figure 2. Furthermore, Applicants have inserted Sequence Identifiers (SEQ ID NOS:) where relevant on pages 3 and 4 of the specification, as indicated above by the replacement paragraphs.

Rejection under 35 USC §101 and §112, 1st paragraph:

The Examiner has rejected claims 4, 8-9, and 24-29 under 35 U.S.C. §101 and §112, 1st paragraph. In summary, the Examiner has stated that the claimed invention is not supported by either a specific, substantial, credible asserted utility or a well-established utility, and, consequently, one skilled in the art would not know how to use the claimed invention.

The Examiner states that the instant claims are drawn to a protein of as yet undetermined function or biological significance, and until some actual and specific significance can be attributed to the protein identified in the specification as SEQ ID NO:2, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. Such a use has been determined by the courts to be a utility which, alone, does not support patentability. Thus, the Examiner states that, since the instant specification does not disclose a credible "real world" use for the ras-like protein of the instant invention, then the claimed invention as disclosed does not meet the requirements of 35 U.S.C. §101 as being useful.

Applicants respectfully traverse this rejection based on the following remarks.

Applicants respectfully assert that the protein of SEQ ID NO:2 has been sufficiently characterized with regard to biological function and significance such that one of ordinary skill in the art can use the claimed invention without undue experimentation, and therefore the claimed invention meets the requirements of 35 U.S.C. §101 and §112, 1st paragraph.

For example, the specification and figures show that the protein of SEQ ID NO:2 functions as a Rho GTPase-activating (RhoGAP) protein. The protein of SEQ ID NO:2 is similar to the Nadrin protein, which is an example of a RhoGAP protein. Nadrin contains a GTPase-activating protein domain for Rho family GTPases, and the GTPase-activating protein domain has been shown to activate RhoA, Rac1, and Cdc42 GTPases *in vitro* (as indicated on lines 13-16 of page 5 of the specification).

In asserting the function of the protein of SEQ ID NO:2, Applicants have relied on several supporting lines of evidence, all of which consistently indicate that the protein of SEQ ID NO:2 functions as a RhoGAP protein. For example, Hmmer/Pfam analysis, provided on page 5 of Figure 2, indicates the presence of a RhoGAP domain. PROSITE analysis, provided on pages 1-2 of Figure 2, identifies the precise locations within SEQ ID NO:2 of glycosylation sites, phosphorylation sites, myristoylation sites, and an aminoacyl-transfer RNA synthetases class-I

signature. Additionally, as shown on page 4 of Figure 2, SEQ ID NO:2 shares 82% sequence identity with the rat Nadrin protein, which is an example of a RhoGAP protein.

The function of RhoGAP proteins, such as Nadrin, is well established in the art and specifically asserted in the specification. For example, Rho proteins are one of five subfamilies within the Ras superfamily (as indicated on lines 11-12 of page 3 of the specification), and Rho proteins are important for controlling signal transduction in the process of linking receptors of growth factors to actin polymerization which is necessary for cell division (as indicated on lines 13-15 of page 3). Furthermore, during cell adhesion, Rho proteins are essential for triggering focal complex assembly and integrin-dependent signal transduction (as indicated on lines 25-27 of page 4). GTPase-activating proteins (including RhoGAP proteins) inactivate Ras proteins (including Rho proteins), which alternate between an inactive form bound to GDP and an active form bound to GTP (as indicated on lines 7-10 of page 2). Thus, because it is well established in the art that RhoGAP proteins are important for inactivating Rho proteins, which are in turn important for regulating signal transduction, cell adhesion, and cell division, it is well established that novel RhoGAP proteins are useful in the treatment, diagnosis, and prevention of cancer.

Thus, since the protein of SEQ ID NO:2 has been functionally characterized in the specification and figures as a RhoGAP protein, and because RhoGAP proteins have well-established and specifically asserted utilities which meet the requirements of 35 U.S.C. §101, Applicants have provided sufficient guidance such that one of ordinary skill can use the claimed invention without undue experimentation. Applicants therefore respectfully request that the Examiner reconsider and withdraw the rejections of claims 4, 8-9, and 24-29 under 35 U.S.C. §101 and §112, 1st paragraph.

Conclusions

Claims 4, 8-9, 13, and 24-29 are presently pending, and claim 13 has been withdrawn from consideration by the Examiner.

The amendments to the specification add no new subject matter and their entry is respectfully requested.

In view of the above remarks and amendments, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the objections and rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,
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